SOP No.: MDP-ADMIN-04		Page 1 of 4	
Title: Laboratory Equipment			
Revision: Original	Replaces: N/A	Effective: 08/15/03	

### 1. Purpose:

To ensure adequate and proper equipment for the conduct of USDA/AMS Microbiological Data Program (MDP) analytical work.

### 2. Scope:

This standard operating procedure (SOP) shall be followed by all laboratories conducting microbiological studies for MDP, including support laboratories conducting non-routine activities that may impact the program.

### 3. Outline of Procedure:

- 5.1 Equipment Design
- 5.2 Equipment Maintenance and Calibration

#### 4. References:

- U.S. EPA, Equipment design, 40 CFR part 160.61, July 1, 1999
- U.S. EPA, Maintenance and calibration of equipment, 40 CFR part 160.63, July 1, 1999

### 5. Specific Procedure

### 5.1 Equipment Design

Equipment used in the generation, measurement, or assessment of data for MDP and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the study protocol and SOPs and shall be suitably located for operation, inspection, cleaning, and maintenance.

- 5.2 Maintenance and Calibration of Equipment.
  - 5.2.1 Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized.
  - 5.2.2 The written SOPs shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when

SOP No.: MDP-ADMIN-04		Page 2 of 4
Title: Laboratory Equipment		
Revision: Original	Replaces: N/A	Effective: 08/15/03

appropriate, remedial action to be taken in the event of failure or malfunction of equipment.

- 5.2.3 Written records shall be maintained of all inspection, maintenance, testing, calibration, and/or standardization operations. These records, containing the dates or the operations, shall describe whether the maintenance operations were routine and followed the written SOPs. Written records shall be kept of non-routine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.
- 5.2.4 Raw data packages shall reflect which specific instruments and equipment were used to generate, measure, or assess the data.
- 5.2.5 Data on the calibration and/or standardization of applicable equipment and instruments is to be included in the raw data packages. Calibration and/or standardization data for balances, refrigerators, and other peripheral equipment does not need to be included in the raw data package.

SOP No.: MDP-ADMIN-04		Page 3 of 4
Title: Laboratory Equipment		
Revision: Original	Replaces: N/A	Effective: 08/15/03

## Grace H all

08/07/03

Approved by: Grace Hall, Chairperson Date MDP Technical Advisory Committee Florida Department of Agricultural and Consumer Services Food Laboratory, Bldg. 9 3125 Conner Blvd.
Tallahassee, Florida 32399-1650 (850) 488-4407

## Roger Fry

08/11/03

Date

for: Approved By: Martha Lamont Director, Monitoring Programs Office 8609 Sudley Road, Suite 206 Manassas, VA 20110

Diana H aynes

08/11/03

Reviewed By: Diana Haynes Quality Assurance Officer, Monitoring Programs Office Date

8609 Sudley Road, Suite 206 Manassas, VA 20110

(703) 330-2300

(703) 330-2300

Original Signature Page Maintained by USDA, AMS, Science & Technology, Monitoring Programs Office Electronically Reproduced Signatures

SOP No.: MDP-ADMIN-04		Page 4 of 4	
Title: Laboratory Equipment			
Revision: Original	Replaces: N/A	Effective: 08/15/03	

SOP No.: MDP-ADMIN-04		Page 5 of 4
Title: Laboratory Equipment		
Revision: Original	Replaces: N/A	Effective: 08/15/03

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• Established laboratory equipment requirements for MDP